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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/508,913	03/16/2000	STEPHEN A. UDEM	33.359-01P	3738

7590

08/27/2002

AMERICAN HOME PRODUCTS CORPORATION  
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EXAMINER

WINKLER, ULRIKE

ART UNIT

PAPER NUMBER

1648

DATE MAILED: 08/27/2002

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Please find below and/or attached an Office communication concerning this application or proceeding.

**Office Action Summary**

Application No.

09/508,913

Applicant(s)

UDEM ET AL.

Examiner

Ulrike Winkler, Ph.D.

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 05 June 2002.
- 2a) ☒ This action is **FINAL**.                      2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1 and 3 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1 and 3 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on \_\_\_\_\_ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

**Priority under 35 U.S.C. §§ 119 and 120**

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

**Attachment(s)**

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) \_\_\_\_\_.
- 4) ☐ Interview Summary (PTO-413) Paper No(s). \_\_\_\_\_.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: \_\_\_\_\_.

### **DETAILED ACTION**

The Amendment filed June 5, 2002 (Paper No. 14) in response to the Office Action of December 5, 2001 is acknowledged and has been entered. Claims 2, 4 and 5-11 have been cancelled. Claims 1 and 3 are pending and are currently being examined.

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office Action.

#### ***Specification***

The Office acknowledges applicants amendment updating the specification.

#### ***Oath/Declaration***

The office acknowledges the submission of a new Oath and Declaration.

#### ***Sequence listing***

Applicant's CRF and paper sequence listing have been entered.

#### ***Claim Rejections - 35 USC § 112***

The rejection of claim 2 under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention is **withdrawn** in view of applicant's amendments to the claims.

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The rejection of claim 1 (note claim 2 has been deleted by the amendment of Paper No. 14) under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for attenuated viral mutants that have multiple mutations (see table 21 and 22), does not reasonably provide enablement for ~~of~~ achieving an attenuated RSV virus by making a single mutation in the RNA polymerase gene **is maintained** for reason of record. Applicant arguments have been fully considered but are not deemed persuasive. Applicant point to the specification page 55, lines 2-16 and 22-33 to indicate that a single recombinant mutation results in the *ts* phenotype. Applicant points to the reversion of a single amino acid as resulting in the phenotype. This is not convincing because the mutations disclosed in table 21 and 22 were first of all not recombinantly generated, ie. they were sequenced from a previously isolated virus that was chemically modified and plaque purified. The sequence also contains other mutations in the same gene region that are not found in the parental strain. Hence to conclude that a single mutation from the parental stain would result in the *ts* phenotype is not convincing. Because 2B33F strain has mutation at locations 353, 451, 1229 and 2029 which results in the *ts* phenotype, a phenotypic reversion at a single location in a region that contains 3 other mutations does not address the possibility that it is only in the context of the other 3 mutations that this single 451 mutation will have this reversion phenotype. 2B20L has mutations at 154, 1616, 2029 and, 2050 single mutation with a *ts* phenotype in the context of at least 3 other mutations in the same gene region. The context of the mutation between the stain 2B20L and 2B33F is very different, hence of ordinary skill cannot predict that the other mutations in the strain are not involved in the expression of the *ts* phenotype. Therefore, the instant invention is not enabled for the full scope of the invention.

***Claim Rejections - 35 USC § 102***

The rejection of claims 1 and 3 (note claims 2 and 4 have been canceled by the amendment of Paper No. 14) are rejected under 35 U.S.C. 102(e) as being anticipated by Randolph et al. (U.S. Pat. No. 5,932,222) **is maintained** for reason of record. Applicant's arguments filed June 5, 2002 have been fully considered but they are not persuasive. Applicant argues that each and every element must be disclosed in the prior art to anticipate a claim. Additionally applicant argues that the prior art has not disclosed the structural characteristic, it has only disclosed the physical characteristics. Applicant cites *ENZO Biochem Inc. v Gene Probe*, 62 USPQ2d 1289 (Fed. Cir. April 2, 2002) indicating that a deposit of a biological material does not suffice as sufficient written description regarding the disclosed the structural elements ie. the DNA sequence. This decision however was overturned in *ENZO Biochem Inc. v Gene Probe*, (Fed. Cir. 01-1230, July 15, 2002), specifically on the point that reference in a patent specification to a deposit of genetic material may suffice to describe that material (see conclusion). Therefore, the rejection is maintained.

The rejection of claims 1 and 3 (note claims 2 and 4 have been canceled by the amendment of Paper No. 14) under 35 U.S.C. 102(b) as being anticipated by Randolph et al. (EP 0 567 100 A1) **is maintained** for reason of record. Applicant's arguments filed June 5, 2002 have been fully considered but they are not persuasive. Applicant argues that each and every element must be disclosed in the prior art to anticipate a claim. Additionally applicant argues that the prior art has not disclosed the structural characteristic, it has only disclosed the physical characteristics. Applicant cites *ENZO Biochem Inc. v Gene Probe*, 62 USPQ2d 1289 (Fed. Cir.

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April 2, 2002) indicating that a deposit of a biological material does not suffice as sufficient written description regarding the disclosed structural elements ie. the DNA sequence. This decision however was overturned in *ENZO Biochem Inc. v Gene Probe*, (Fed. Cir. July 15, 2002), specifically on the point that reference in a patent specification to a deposit of genetic material may suffice to describe that material (see conclusion). Therefore, the rejection is maintained.

### ***Double Patenting***

The rejection of claims 1 and 3 under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claim 7-10 of U.S. Patent No. 5,932,222. Although the conflicting claims are not identical, they are not patentably distinct from each other because The instant invention is drawn to an isolated, attenuated human RSV subgroup B virus which has at least one attenuating mutation in the RNA polymerase gene. For this office action, the preamble reciting "recombinantly-generated" is interpreted as a product-by-process, therefore, claims 1 and 3 were interpreted as "an isolated attenuated RSV virus" (which is a *product*). Product-by-process claims are not limited to the manipulations of the recited steps, only to the structure implied by the steps (see above). Randolph et al. disclose the mutation, characterization and isolation of various *ts* attenuations of RSV subgroup B virus. These attenuated viruses have been deposited with ATCC under the following accession numbers #VR2364 (=2R33F) and #VR2365 (=2B20L). The reference discloses using these attenuated viruses as a vaccine formulation (see claims 7-10). Applicant argues that each and every element must be disclosed in the prior art to anticipate a claim. Additionally applicant argues that the

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prior art has not disclosed the structural characteristic, it has only disclosed the physical characteristics. Applicant cites *ENZO Biochem Inc. v Gene Probe*, 62 USPQ2d 1289 (Fed. Cir. April 2, 2002) indicating that a deposit of a biological material does not suffice as sufficient written description regarding the disclosed the structural elements ie. the DNA sequence. This decision however was overturned in *ENZO Biochem Inc. v Gene Probe*, (Fed. Cir. July 15, 2002), specifically on the point that reference in a patent specification to a deposit of genetic material may suffice to describe that material (see conclusion). Therefore, the rejection is maintained.

### ***Conclusion***

No claims are allowed.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event,

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however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Ulrike Winkler, Ph.D. whose telephone number is 703-308-8294.

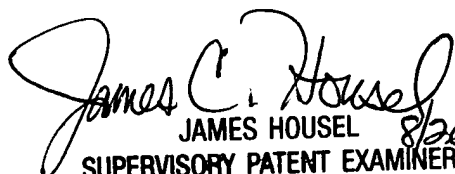
The examiner can normally be reached M-F, 8:30 am - 5 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, James Housel, can be reached at 703-308-4027.

The fax phone numbers for the organization where this application or proceeding is assigned are 703-308-4242 for informal communications use 703-308-4426.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0196.

Ulrike Winkler, Ph.D.

  
JAMES HOUSEL 8/26/02  
SUPERVISORY PATENT EXAMINER  
TECHNOLOGY CENTER 1600